

Remarks:

The claims have been amended slightly for clarification or emphasis of what was already believed to be implicit therein and to correct the dependencies of some claims.

Favorable reconsideration is requested of the rejection of claims 39, 41, 43-45, 47-49, 51-54, 56-63, and 66 as being anticipated by the Olstein patent (U.S. patent 5,142,010). An anticipation rejection requires that a single prior art reference disclose *every* element of the claim. The Examiner has admitted that each of the claims of this rejection calls for a linkage group that differs from that of the polymers of the Olstein patent. Accordingly, the Olstein patent cannot anticipate the rejected claims.

While the Examiner argues that the criticality of the linkage group has not been established, criticality is not required with respect to an anticipation rejection. The Court of Appeals for the Federal Circuit has repeatedly emphasized that a claim is anticipated *only if all* the elements of the claim¹ are *identically* set forth² in a *single* prior art reference.³ As stated in §3.02[1][b] of *Chisum on Patents*, anticipation requires *strict* identity of the elements, not

¹ See *Chisum on Patents* §3.02[1][b] and cases at fn. 10, citing, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 62 USPQ2d 1865 (Fed. Cir. 2002); *Sandt Technology, Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 60 USPQ2d 1091 (Fed. Cir. 2001); *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350, 60 USPQ2d 1423 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); *Rapoport v. Dement*, 254 F.3d 1053, 1057, 59 USPQ2d 1215 (Fed. Cir. 2001) ("To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently."); *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1383, 59 USPQ2d 1130 (Fed. Cir. 2001) ("Normally, to invalidate a patent by anticipation a prior art reference needs to disclose each and every limitation of the claim."); *et al.*

² See *Chisum on Patents* §3.02[1][b] and cases at fn. 11, citing, e.g., *Gechter v. Davidson*, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) ("Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim."); *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 45 F.3d 1550, 1554, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995) ("Anticipation requires identity of the claimed process and a process of the prior art; the claimed process, including each step thereof, must have been described or embodied, either expressly or inherently, in a single reference."); "Anticipation ... requires identity of invention: the claimed invention, as described in appropriately construed claims, must be the same as that of the reference, in order to anticipate."; *et al.*

³ See *Chisum on Patents* §3.02[1][b] and cases at fn. 12, citing, e.g., *Mehl/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1306 (Fed. Cir. 1999) ("To anticipate, a single reference must teach every limitation of the claimed invention."); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (Fed. Cir. 1999); *Finnigan Corp. v. U.S. Int'l Trade Comm'n*, 180 F.3d 1354, 1367, 51 USPQ2d 1001, 1009 (Fed. Cir. 1999) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); *et al.*

substantial similarity or even substantial identity: "Federal Circuit decisions, explicitly or implicitly, reject any standard of 'substantial identity.'"⁴

In any event, although the Examiner has simply and without support stated that the claimed linkages are not critical to the invention, the linkage types do differ significantly. Moreover, the claims distinguish over the Olstein patent in other significant respects as well. For example, all the rejected claims call for the linkages to be bound to the secondary nitrogens of the biguanide as opposed to the terminal primary nitrogens as in the Olstein patent.⁵

⁴ Chisum on Patents §3.02[1][b] at fn. 13. See also the footnote itself: "*Key Pharmaceuticals v. Hercon Laboratories Corp.*, 161 F.3d 709, 718-19, 48 USPQ2d 1911, 1919 (Fed. Cir. 1998) (claim to a "drug in adhesive" transdermal patch requiring a dosage of at least 2.5 mg/day is not anticipated by a reference showing a patch with a dosage calculated to deliver a maximum of 2.0 mg/day; the infringer argued that the prior art reference "would merely have to be increased in size by 25 percent to deliver 2.5 mg/day, and ... this is inherently taught by ... the ... reference. However, as the trial court's findings indicate, these assertions lack the kind of support in the record needed for proof of invalidity by clear and convincing evidence."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) (the district court correctly found a patent's claims not anticipated but it "did not articulate the correct legal standard when it stated that to invalidate a patent the prior reference must 'give the same knowledge and the same directions' as the challenged patent."; "To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."); *Credle v. Bond*, 25 F.3d 1566, 1578, 30 USPQ2d 1911, 1921 (Fed. Cir. 1994) (a reference that discloses a "flexible" element does not anticipate a claimed invention that requires that the element be "flexibly" secured to an object. "Nothing ... prevents the existence of a perfectly secure, inflexible bond between the end of a flexible member and another inflexible object ..."); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991) ("Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference... . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention."); *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236-37, 9 USPQ2d 1913, 1920-21 (Fed. Cir. 1989), cert. denied, 493 U.S. 853 (1989) (the district court erroneously instructed the jury that anticipation may be shown "by equivalents", which is "a legal theory that is pertinent to obviousness under Section 103, not to anticipation under Section 102."; "The jury requested a definition of 'equivalent' during its deliberations, and was given the Webster's dictionary definition 'corresponding or virtually identical, especially in effect or function.' This narrow definition, which does not accord with that of *Graver Tank*, [the leading Supreme Court decision on infringement under the doctrine of equivalents,] may have minimized the legal error in the instructions."; "Every element of the claimed invention must be literally present, arranged as in the claim."); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985) (citing *Treatise*: "anticipation under § 102 can be found only when the reference discloses exactly what is claimed"; "where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account")."

⁵ It is clear from the subject specification that the references to "primary" and "secondary" refer to the nature of the nitrogen as shown in the formula shown without the moiety in question bonded thereto. Thus, for example, the imino nitrogen ($R_1R_2C=NH$) and the intermediate nitrogen ($-C-NH-C-$) within the biguanide group of the formula shown in the specification and claims are referred to in the specification and claims as secondary even though after the bonding through the noted linkages, they are tertiary nitrogen, and the terminal nitrogens ($R-C-NH-$) within the biguanide group of the formula shown in the specification and claims are referred to in the specification and claims as primary even though after the bonding with, as shown at the top of page 5 of the subject specification for example, two hexamethylene groups (in the case of polyhexanide) or to one hexamethylene group and one 4-chlorophenyl group (in the case of chlorhexidine) they are secondary nitrogens. Thus, the nitrogen of the group A-Q-NH- and the nitrogen of the group -NH-R of the formula set forth in the Olstein patent correspond to what are referred to in the subject specification as the terminal or primary nitrogen groups of the biguanide.

With respect to the linkage type, the rejected claims call for the linkages to be substituted urea linkages, substituted thiourea linkages, N,N-disubstituted amide linkages, N,N-disubstituted hemiaminal or aминаl linkages, or tertiary amine linkages. By contrast, the linkages of the Olstein patent are aromatic linkages –i.e., phenylene linkages- between a biguanide amino nitrogen and a polymer-forming compound such as shown in Formula VIII of the Olstein patent (where A is a polymerizable moiety and Q is the $-C_6H_4-$ aromatic group). Thus, whereas the rejected claims call for certain aliphatic linkages to the intermediary secondary nitrogens of the biguanide, the Olstein patent shows aromatic linkages to the terminal $-NH-$ amino groups of the unsymmetrical biguanide. There is no reason to believe that two such vastly different formulae would have similar properties.

Applicant has amended the claims slightly to emphasize that the linkages are bound to *secondary* nitrogens of applicant's biguanides. Thus, the claims clearly call for some of the secondary nitrogens to be linked via the noted linkages to a polymer chain. As can be seen from applicant's preferred biguanides set forth at the top of page 5 of the specification, the terminal primary nitrogens may be linked, for example, to two hexamethylene groups (in the case of polyhexanide) or to one hexamethylene group and one 4-chlorophenyl group (in the case of chlorhexidine).

Thus, with particular reference to the present invention as defined by claim 39, the present invention is directed to a polymeric material incorporating an infection-resistant biguanide pendant to a polymer chain and chemically bound to the chain by means of a substituted urea linkage, a substituted thiourea linkage, an N,N-disubstituted amide linkage, an N,N-disubstituted hemiaminal or aминаl linkage, or a tertiary amine linkage to some but not all of the secondary amine nitrogen atoms of the $-NH-C(NH)-NH-C(NH)-NH-$ biguanide group or groups of the infection-resistant biguanide. By contrast, the Olstein patent discloses not a polymer chain bearing pendant biguanide groups bound thereto by their secondary nitrogens via the noted linkages, but rather a polymerizable unsymmetric biguanide monomer that can be co-polymerized with other monomers via a polymerizable group at a primary nitrogen at the end of the biguanide group. That polymerizable group is identified in the Olstein patent as A-Q-, wherein $-Q-$ is a phenylene (although the Olstein patent refers to Q being “generally” phenylene, col. 2, line 56, phenylene is the only $-Q-$ identified or suggested), and A- is a polymerizable group such as alkoxysilane moieties, isocyanate moieties, vinyl moieties, epoxy groups, aziridine groups, polymerizable groups containing an active hydrogen, and certain amides.

Accordingly, the Examiner appears to suggest that a phenylene linkage between a primary, terminal biguanide amino nitrogen and a polymer-forming moiety as shown in Formula VIII of the Olstein patent and pendant biguanides linked by aliphatic groups to a polymer chain. It is not seen how such polymers are in any way equivalent. Moreover, Applicants' polymers provide several advantages over the polymers disclosed by the Olstein patent. For example, by contrast to the polymers of Olstein, Applicants' polymers retain biguanide antimicrobial activity in a polymer that can be produced conveniently. Thus, while the Olstein products are produced by synthesis of monomers (col. 7, lines 48 and following) using an unsymmetrical biguanide feedstock and proceeding through several steps. Indeed, production of the unsymmetrical biguanide itself may even require several steps as illustrated by the Examples of the Olstein patent. The overall process yields are not readily apparent, but in all cases in the Olstein patent a multiplicity of steps is employed to produce the desired polymerizable end products. As a result, the class of products to which the Olstein patent is directed is inconvenient and the production of such products is likely to be inefficient.

In fact, the products of the Olstein patent are of a different class than those of the subject claims. The Olstein products are specifically built around binding to a polymer chain through a phenylene moiety bound to a primary amine nitrogen, resulting in a secondary amine linkage. By contrast, Applicants' products contain linkages to a polymer chain via secondary amine nitrogens by reaction with the sole hydrogen on the nitrogen to produce a tertiary nitrogen linkage, thereby permitting simple preparation. The preparation is direct and efficient. For example, chemical modification may be carried out on commercially available polyhexanide and chlorhexidine, both of which have proven broad ranges of antimicrobial activity, without materially altering the antimicrobial activity of the biguanides. Further, a preliminary step in the preparation of Applicants' polymeric materials forms a partial free base of the commercially available biguanide before binding the reactive species with the nitrogen of the secondary amine. By removing some but not all of the acid of the usual acid addition salt of the biguanide, some of the secondary amine nitrogens are available for chemical reaction.

In sum, the present invention uses secondary amino nitrogens of antimicrobial biguanide groups to anchor them as pendant groups to polymeric or monomeric substances without affecting the antimicrobial activity of the biguanide groups and by means of linkages Applicants have discovered permit this. The Olstein patent nowhere teaches or suggests such compositions.

Therefore, claim 39 distinguishes patentably over the Olstein patent in several respects. Not only does the Olstein patent fail to teach or to suggest bonding via the linkages identified by claim 39, but the Olstein patent also fails to teach or to suggest any reaction or bonding at the secondary nitrogens of the biguanides as called for by claim 39. Nor does the Olstein patent teach or suggest that the biguanide groups be pendant to a polymer chain as called for by claim 39. Accordingly, claim 39 is not anticipated by or obvious over the Olstein patent, but rather defines patentably over the Olstein patent. The remaining claims under the subject rejection either depend from or otherwise include the features of claim 39 that distinguish patentably over the Olstein patent as discussed above, plus add further features. Thus, it is submitted that all remaining rejected claims distinguish patentably over the Olstein patent for at least the reasons discussed above.

Favorable reconsideration is also requested of the rejection of claims 39, 41, 46, 50 and 55 as being anticipated by the British patent to Buckley et al. ("Buckley"). As noted above, anticipation requires that a single prior art reference disclose *every* element of the claim. As also noted above, all present claims call for biguanides to be pendant to a polymer chain. By contrast, the biguanide groups of Buckley are in line with and are part of the polymer chain. Moreover, while the Examiner notes the possibility of the presence of amides or urea linkages within the polymer, this in no way teaches or even suggests that such linkages connect directly to a secondary amine nitrogen of a biguanide group pendant to a polymer as a result of such linkages, as required by all pending claims. Thus, claims 39, 41, 46, 50 and 55 distinguish patentably over Buckley.

Favorable reconsideration is also requested of the rejection of claims 40, 42, 48, 64 and 65 as being obvious over the Olstein patent in view of the Solomon et al. patent (US patent 5,451,424). Several deficiencies in the Olstein patent are discussed above. The Solomon et al. patent nowhere teaches or suggests any remedy for such deficiencies.

Moreover, the Solomon et al. patent does not even teach or suggest what it has been cited for. It is not seen that identification of particular biguanides beyond the disclosure of the Olstein patent is necessary, but the Solomon et al. patent has been cited for such teaching. While the Examiner, relying on the abstract of the Solomon et al. patent, states that the Solomon et al. patent discloses a biguanide polymer comprising chlorhexidine, such is not the case. Solomon et al. state that chlorhexidine is bulk-distributed throughout a polymeric layer of polyurethane and that chlorhexidine may be permeated into the surface. The Solomon et al. patent makes clear

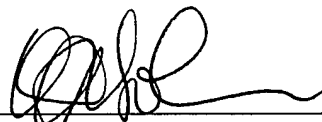
that chlorhexidine is blended into a polyurethane article and not chemically bonded to it in any way. Thus, while the Examiner states that “the biguanide is bound to polyurethane,” the actual disclosure is that the biguanide is blended into polyurethane.

In paragraph 13 of the Office Action, it is stated that no criticality of the linkage or “coupling” agents is seen. First, this has been addressed above. Second, as also discussed above, all pending claims include further distinctions over the Olstein patent beyond the nature of the linkages or coupling agents –distinctions that the Solomon et al. patent does not resolve. Third, a lack of criticality is not a proper basis for an obviousness rejection. The rejection should show the feature of the claim missing from the primary reference in another reference and a reason to combine the teachings. Thus, the discussion in paragraph 13 of the Office Action does not support a finding of obviousness.

In paragraph 14 of the Office Action, the Examiner states that “it would have been obvious to incorporate the biguanides of the [Solomon et al. patent] into the preparation of the [Olstein patent] . . .” Presumably, the Examiner means that the biguanides of the Solomon et al. patent can be substituted for those of the Olstein patent. However, the Olstein patent does not show biguanides pendant to a polymer chain as called for in all pending claims. Nothing in either reference teaches or suggests a polymer chain with any type of pendant biguanides pendant thereto via certain linkages to the secondary amines of the biguanides. Thus, the discussion in paragraph 13 of the Office Action does not support a finding of obviousness.

In view of the foregoing, it is submitted that all pending claims define patentably over the art of record and are in condition for allowance. Accordingly, favorable reconsideration and withdrawal of all outstanding rejections and early allowance are earnestly solicited.

Respectfully submitted,



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